10/009881

JC10 Rec'd PCT/PTO 13 NOV 2001

JORDAN AND HAMBURG LLP
122 East 42nd Street,
New York, NY 10168
Tel: (212) 986-2340 Fax: (212) 953-7733
Customer No.: 000028107

Docket No.: F-7212
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THE ASSISTANT COMMISSIONER FOR PATENTS
Washington, D. C. 20231

[ ] ATTN: BOX PATENT APPLICATION

[ ] ATTN: BOX DESIGN PATENT APPLICATION

[X] ATTN: BOX PCT

[X] THIS IS THE 35 U.S.C 371 NATIONAL STAGE OF **PCT/EP00/04166** FILED **May 10, 2000**

Sir:

Transmitted herewith for filing is the [X] Utility [ ] Design nonprovisional patent application of:

Inventor / Application Identifier: **Peter LITSCHKO, et al.**

[X] See Inventor Information Sheet attached

For: **METHOD FOR GENERATING PATIENT-SPECIFIC IMPLANTS**

[ ] This is a new patent application.
[X] This is the 35 U.S.C. 371 National Stage Application of the above-identified PCT Application.
[ ] This is a: [ ] Continuation Application
[ ] Divisional Application
[ ] Continuation-in-Part Application
of prior Application Serial No. _.

[ ] Cancel in this application original claims ___ of the prior application before calculating the filing fee.

[ ] Amend the specification by inserting before the first line the sentence:
-- This is a [ ] Continuation, [ ] Division, [ ] Continuation-in-part, of Application

[ ] Incorporation By Reference. The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

JC13 Rec'd PCT/PTO 13 NOV 2001

ENCLOSED ARE THE FOLLOWING:		
X	5	Sheets of drawings ([X] formal [ ] informal size A4).
X	14	Pages of specification including abstract and claims.
X	19	Total pages.
	Combined Declaration and Power of Attorney	
		Newly executed
		Copy from prior application
		Inventors deleted; see attached statement
	Sequence Listing	
		Computer Readable Copy
		Paper copy
		Statement verifying identity of above copies
X	Return Receipt Postcard	
X	Preliminary Amendment	
	Assignment to:	
		Assignment is of record in prior application Serial No._.
		Assignment Recordation Form Cover Sheet.
		Charge $40.00 to Deposit Account No. 10-1250 for recording Assignment.
X	Information Disclosure Statement	
X	Information Disclosure Citation	
	English translation	
X	Application Data Sheet	

PRIORITY CLAIMS		
		Applicant hereby claims the benefit of the filing date of the following provisional application(s) under the provision of 35 USC 119.
X		Applicant hereby claims the benefit under the provisions of 35 USC 119 of the filing dates of the following applications as indicated below: **Germany Patent Appln. No. 199 22 279.7, filed May 11, 1999, Priority Claimed** of which certified copies thereof
		will follow
		are enclosed
	X	have been filed in the International Bureau
		were filed in prior application:

CLAIMS FILED AND FILING FEE CALCULATION					
ITEM	—			Rate	Applied Fee
[ ] Base Fee - Non PCT	—			$740	
[ ] Base Fee - PCT IPEA-US	—			$710	
[ ] Base Fee - PCT ISA-US	—			$740	
[ ] Base Fee - PCT not ISA or IPEA	—			$1,040	
[X] Base Fee - PCT with EPO or JPO Search Report	—			$890	$890
[ ] Base Fee - Design	—			$330	
Claim Fees	Number Filed	Base Number	Number Extra over Base	—	
Total Claims	7	20	0	$18	$0
Independent Claims	1	3	0	$84	$0
Multiple Dependent Claim Fee	—			$280	$280
[ ] Small Entity Status is Asserted	—				($0)
[ ] Foreign Language Filing Fee	—			$130	$0
TOTAL FILING FEE					**$1,170**

[X] Please charge Deposit Account No. 10-1250 in the amount of the above TOTAL FILING FEE. A duplicate copy of this sheet is attached.

[X] Please charge to Deposit Account No. 10-1250 any further fees due for filing or during prosecution of this application under: 37 CFR 1.16; 37 CFR 1.17; and 37 CFR 1.492.

JORDAN AND HAMBURG LLP

By _____
C. Bruce Hamburg
Reg. No. 22,389
Attorney for Applicant

10/009881

JC13 Rec'd PCT/PTO 13 NOV 2001

INVENTOR INFORMATION SHEET

Docket Number: F-7212
Title: METHOD FOR GENERATING PATIENT-SPECIFIC IMPLANTS
Filing Date: 11/13/01

1. Full Name of Inventor **Peter LITSCHKO**	Family Name **LITSCHKO**	First Given Name **Peter**	Second Given Name
Citzenship **Germany**	Residence City **Naumburg**	Residence State or Province	Residence Country **Germany**
Postal Address **Weingarten 10**	City **Naumburg**	Province/State	Postal Code/Country **D-06618 Germany**
2. Full Name of Inventor **Torsten HENNING**	Family Name **HENNING**	First Given Name **Torsten**	Second Given Name
Citzenship **Germany**	Residence City **Jena**	Residence State or Province	Residence Country **Germany**
Postal Address **Berghoffsweg 6A**	City **Jena**	Province/State	Postal Code/Country **D-07743 Germany**
3. Full Name of Inventor **Joerg BEINEMANN**	Family Name **BEINEMANN**	First Given Name **Joerg**	Second Given Name
Citzenship **Germany**	Residence City **Weimar**	Residence State or Province	Residence Country **Germany**
Postal Address **Hoher Weg 11**	City **Weimar**	Province/State	Postal Code/Country **D-99425 Germany**
4. Full Name of Inventor **Wolfgang FRIED**	Family Name **FRIED**	First Given Name **Wolfgang**	Second Given Name
Citzenship **Germany**	Residence City **Jena**	Residence State or Province	Residence Country **Germany**
Postal Address **Julius-Schaxel-Strasse 25**	City **Jena**	Province/State	Postal Code/Country **D-07749 Germany**

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INVENTOR INFORMATION SHEET

Docket Number: F-7212
Title: METHOD FOR GENERATING PATIENT-SPECIFIC IMPLANTS
Filing Date: 11/13/01

5. Full Name of Inventor **Werner LINSS**	Family Name **LINSS**	First Given Name **Werner**	Second Given Name
Citzenship **Germany**	Residence City **Jena**	Residence State or Province	Residence Country **Jena**
Postal Address **Sachseneckweg 4**	City **Jena**	Province/State	Postal Code/Country **D-07743 Jena**

F-7212

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Peter LITSCHKO et al.
Serial No.	:	Not yet known (U.S. National Stage of PCT/EP00/04166 filed May 10, 2000)
Filed	:	Not yet known
For	:	METHOD FOR GENERATING PATIENT-SPECIFIC IMPLANTS

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Preliminary to examination, please amend the above-identified patent application as follows:

IN THE CLAIMS:

Amend claims 1-4 as follows, the amendments being shown by brackets and underscoring in the Appendix I hereto:

1. (Amended) Method for manufacturing a patient-specific implant, comprising generating a virtual three-dimensional model from image data of at least the patient's implant area and the environment thereof, comparing the virtual three-dimensional model to real medical reference data, selecting from the real medical reference data a set of said reference data best suited for the patient and forming a reference model object therefrom, generating a virtual implant model

from said reference model object, and manufacturing the implant by computer numeric control based on data from the virtual implant model.

2. (Amended) Method as claimed in claim 1, wherein the real medical reference data comprise a database.

3. (Amended) Method as claimed in claim 2, wherein the selecting comprises first selecting a plurality of sets of said reference data suited for the patient and then applying further selection criteria to select from said plurality of sets said set best suited for the patient.

4. (Amended) Method as claimed in claim 1, 2, or 3, wherein the real medical reference data comprises data from the patient.

Cancel claim 5.

Add claim 6 as follows:

--6. Method as claimed in claim 1, wherein the selecting comprises first selecting a plurality of sets of reference data and forming a corresponding plurality of reference model objects therefrom most resembling the patient considering mathematical, functional, medical and aesthetic parameters and then selecting one of said plurality of reference model objects based on expert medical opinion, and

the generation of the virtual implant model is effected by superimposing said one reference object and the virtual three-dimensional model.--

IN THE ABSTRACT:

Delete the original abstract and substitute therefor the abstract appended hereto on a separate sheet.

REMARKS

The claims have been amended with respect to formalities, namely, to eliminate improper multiple dependencies, eliminate redundancies, eliminate the "characterized in that" format for which there is no current legal precedent in the U.S., provide antecedent bases for various recitations in the claims and eliminate narrative claiming.

Claim 6 corresponds in substance to claim 1 as amended under Article 34 in the international stage.

Appendix II hereto shows claims 1-4 and 6, as pending.

Respectfully submitted,

Jordan and Hamburg LLP

By _____
C. Bruce Hamburg
Reg. No. 22,389
Attorney for Applicants

122 East 42nd Street
New York, New York 10168
(212) 986-2340

F-7212

APPENDIX I

AMENDED CLAIMS WITH AMENDMENTS INDICATED THEREIN BY BRACKETS AND UNDERLINING

1. (Amended) Method for [generating] manufacturing a [patent-] patient-specific implant, [in which] comprising generating a virtual three-dimensional model [is generated] from [the] image data [taken] of at least [from] the patient's implant area and [its] the environment [obtained from the patient and the implant is manufactured by virtue of CNC-data for the operative use on the patient, characterized in that] thereof, comparing the virtual three-dimensional model [of the patient is compared] to real medical reference data, selecting from the real medical reference data a set of said reference data [and therefrom the] best suited for the patient and forming a reference model object[, respectively, best resembling the model of the patient are selected or formed] therefrom, [and in that] generating a virtual implant model [is generated by] from said reference model object, and [in that the virtual data of] manufacturing the implant [model are used as] by computer numeric control based on data [for a program controlled manufacture of] from the virtual implant model.

2. (Amended) Method as claimed in claim 1, [characterized in that the virtual three-dimensional model of the patient is compared to] wherein the

real medical reference data [of] comprise a database [and from these data stored in the database a reference model best suited for the patient and best resembling the model of the patient, respectively, is selected].

3. (Amended) Method as claimed in claim 2, [characterized in that at first a plurality of reference models objects resembling the model of the patient are selected from the data stored in the database and from the selected ones a reference model object] wherein the selecting comprises first selecting a plurality of sets of said reference data suited for the patient and then applying further selection criteria to select from said plurality of sets said set best suited for the patient [and mostly resembling the model of the patient, respectively, is selected under consideration of further selection criteria such as medical expert opinion].

4. (Amended) Method as claimed in claim 1, [characterized in that the virtual three-dimensional model of the patient is compared with] 2, or 3, wherein the real medical reference data comprises data from the patient [him/herself preferably under consideration of body symmetry, in particular of mirror-symmetrical body ranges being doubly present and/or under

consideration of older data from the patient and that from these data a reference model object best suited for the patient and most resembling the model of the patient, respectively, is selected or formed].

APPENDIX II

ALL PENDING CLAIMS WITH AMENDMENTS EFFECTED THEREIN

1. Method for manufacturing a patient-specific implant, comprising generating a virtual three-dimensional model from image data of at least the patient's implant area and the environment thereof, comparing the virtual three-dimensional model to real medical reference data, selecting from the real medical reference data a set of said reference data best suited for the patient and forming a reference model object therefrom, generating a virtual implant model from said reference model object, and manufacturing the implant by computer numeric control based on data from the virtual implant model.

2. Method as claimed in claim 1, wherein the real medical reference data comprise a database.

3. Method as claimed in claim 2, wherein the selecting comprises first selecting a plurality of sets of said reference data suited for the patient and then applying further selection criteria to select from said plurality of sets said set best suited for the patient.

4. Method as claimed in claim 1, 2, or 3, wherein the real medical reference data comprises data from the patient.

6. Method as claimed in claim 1, wherein the selecting comprises first selecting a plurality of sets of reference data and forming a corresponding plurality of reference model objects therefrom most resembling the patient considering mathematical, functional, medical and aesthetic parameters and the n selecting one of said plurality of reference model objects based on expert medical opinion, and the generation of the virtual implant model is effected by superimposing said one reference object and the virtual three-dimensional model.

ABSTRACT

An implant is generated which is functionally and aesthetically adapted to the patient with a greater degree of precision, irrespective of the size, form and complexity of the defect, whereby the implant can be produced and operatively inserted into the patient over a short time period and in a simple manner. A virtual three-dimensional model of the patient which is formed from existing recorded (two-dimensional) image data of the patient is compared with real medical reference data. The comparison which is, for example, carried out using a data bank with test person data enables a reference model object which is most suited to the patient or closest to the patient model to be selected or formed and a virtual implant model is generated accordingly. Computer numeric control data is directly generated from the implant model which is generated virtually in the computer for program-assisted production of the implant.

METHOD FOR GENERATING PATIENT-SPECIFIC IMPLANTS

BACKGROUND OF THE INVENTION

The present invention relates to the generation of patient-specific implants based on the examination findings on a patient obtained by imaging methods in medical technology.

It has been possible for long to use, to a limited degree, exogenic material (implants) to close organ defects. The recent state of art is to generate hard-tissue implants specifically adapted to a patient either by obtaining the implants during a surgical operation under use of existing intermediate models or, more recently, under use of CAD/CAM technologies as an aid in computer-aided reconstruction. Imaging methods of the medical technology, such as computer tomography, nuclear magnetic resonance tomography, and sonography increasingly form the basis for generation.

It is common medical practice (refer to, for example, US 4,097,935 and US 4,976,737) to use as implants plastic and workable, respectively, metal webs and metal plates, easily to form materials that have a short curing time (for example, synthetic resin) and endogenic material from the patient by which the defects are closed during the surgical operation, i. e. the implant is obtained during the operation, formed and adapted to the defect. However, metallic implants such as webs and plates etc. can be very disturbing at later diagnosises on the patient and can even render impossible to carry out future special methods of

examination, in particular, when larger defect areas are concerned. The progress of operation is usually dependent on the situation of treatment itself, and the experience of the surgeon. In such cases it is scarcely possible to have a specific operation planning for the insertion of the implant in advance. Therefore the operated on patient occasionally has to undergo follow-up treatments that are an additional physical and psychological strain for the patient. Moreover, some materials, such as synthetic materials which are easily to form and/or can be produced at comparatively low expenditures, can only be utilized in a limited degree with respect to their loadability and endurance. Additionally, there is the desire of the patient to get an aesthetic appearance which in many cases is very hard to realize.

Furthermore, "Stereolithographic biomodelling in cranio-maxillofacial surgery, a prospective trial", Journal of Cranio-Maxillofacial Surgery, 27, 1999 or US 5.370.692 or US 5.452.407 or US 5.741.215), it is possible to start the design of the implant by generating a physical three-dimensional intermediate model, for example, by stereolithographic methods based on medical imaging methods mentioned at the beginning. Then the implant is manually modeled in the defect site by use of plastic workable materials and only then the implant is finally manufactured from the implant material. Thereby the implant preferably is produced from materials of a higher strength, such as titanium.

Furthermore, there is known ("Schädelimplantate - computergestützte Konstruktion und Fertigung", Spektrum der Wissenschaft, Februar 1999; "Die Rekonstruktion kraniofazialer Knochendefekte mit

individuellen Titanimplantaten", Deutsches Ärzteblatt, September 1997), to generate a simple three-dimensional CAD patient model from the data obtained by applying imaging methods on a patient, and to use these data to manually design the implant by computer under use of simple design engineering methods. Subsequently the implant is manufactured for the surgical operation by a computer numeric control (CNC) process.

The methods mentioned hereinbefore, however, have the common disadvantage that the result of the implant-modelling predominantly depends on the experience, the faculty and the "artistic" mastership of the person generating respectively producing said implant. The manufacturing, starting from the data obtained and up to the operationally applicable and mating implant, requires high expenditures of time and cost which are still increased when there is manufactured a so-called intermediate model. The manufacture of an implant during an operation requires correspondingly high expenditures of time and executive routine for the surgical intervention and, thus, means a very high physical and psychological strain, last not least for the patient. Moreover, it is still more difficult to operatively and form-fittingly insert an implant, non-mating to the defect site on the patient, while attending to medical and aesthetic aspects. Also here the special skill and experience of the surgeon very often will be decisive for the outcome of the operation. Practically and in the frame of the clinical routine, the first-mentioned methods can only be used with narrow and/or lowly structurized defects and they will very soon reach their

technological limits with complicated defects and implants as concerns shaping and fitting.

The operative expenditure is greatly dependent on the adaptability of the implant to the defect site. But with a manufacture of an implant via intermediate models this precision can be additionally deteriorated due to copying the intermediate model.

In complicated cases the implants have to be manufactured in lengthy and extremely time-consuming processes and, if necessary, via a plurality of intermediate stages. Within this comparatively long period the defect area on the patient can possibly change in the meantime. These changes, in practice, cannot be sufficiently taken into consideration as concerns the adaptability of the implants and additionally increase the operation expenditures.

From the viewpoint of the surgeon as well as of the patient it will be desirable that the implants should be manufactured in the shortest possible time, also with respect to the surgical intervention, and with a high adaptability to the defect site on the patient. Concrete information not only about the defect site on the patient but also to the size and shape of the implant to be inserted should be available to the attending surgeon for planning the operation in advance and before the intervention on the patient.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an implant generated to be functionally and aesthetically more precisely adaptable to a defect site on a patient, said implant being independent of the size, shape and

complexity of said defect site, whereby said implant can be manufactured and inserted into a patient in one operation process in a shorter time and with less expenditures. The method should be applicable with a same accuracy for all shapes, sizes and for all suitable implant materials.

The present invention provides a virtual three-dimensional model of the patient which is compared to actual medical reference data, whereby the model is formed from known (two-dimensional) image data taken at least from its implant area and environment. The model best suited for the patient and a reference model object, respectively, best resembling the model of the patient are selected from this comparison and a virtual implant model is generated according to this model. From the virtual implant model data present in the computer, computer numeric controlled (CNC) data are on-line produced for a program controlled manufacture of the implant. The real-medical reference data can be compared in a database to the medical data taken from a number of probands (third persons) as well as to the data from the patient him/herself, whose body symmetry (in particular mirror-symmetrical body regions, doubly present) is taken into consideration with respect to the selection for and generation of, respectively, a patient reference model. Even data, which do not show this defect or are indicative of changes in the same, can be used for this comparison.

In this way the implant is virtually customized modeled in a very short time under aesthetic and functional aspects and only by computational expenditures (software). Furthermore, the implant is very accurately

adapted to the shape of the defect site on the patient as concerns any desired form, size and degree of complexity of the required implant. By means of the virtual implant model, which has been generated and adapted to the defect site and to typical reference data, respectively, by CAD/CAM, the attending surgeon can obtain very concrete data for a physical planning of the operation on the virtual model. He can already simulate the progress of an operation in advance of the intervention so that the proper operation and its progress can be better prepared, carried out and its success evaluated more realistically and, if necessary, to have it discussed with the patient a priori and agreed upon. The implant model is extracted from the virtual reference model of the patient by employing mathematical algorithms. Therefrom the control data for the implant, which has to fill respectively to close the defect site, are on-line deduced.

Thus, the implant can be physically and program-controlled manufactured on-line by exploiting the advantages of CNC which is known per se. Thereby it is not necessary to have any intermediate models or test models (in particular for copying, for tests, for improvements and for corrections as well as for a new manufacture, if necessary). Implants of nearly any desired form and size as well as made of any desired material, including ceramics and titanium, can be manufactured by computer numerical controlled (CNC) production machines into which the data input is computer aided. Thus the implant can be selected for each patient with respect to the required properties (function, strength, absorbability, endurance, aesthetic appearance, biological compatibility etc.). The generation of the implant, which is

thus obtained in a very short time and which can be repeated just as quickly under new or changed aspects of the operative intervention, thus reduces the time and routine schedule in the clinical work. Furthermore, the stress for the surgeon and the health risk for the patient are reduced, too. In particular, from the viewpoint of the patient it is a further advantage that a high aesthetic of the implanted defect area is obtained by the accurate adaptation of the implant to be generated to the defective range, and that surgical corrections, refinements as well as other follow-up operations are avoided or at least reduced as to their extent and number.

DETAILED DESCRIPTION OF THE INVENTION

In the following, the invention will be explained in more detail by virtue of the embodiments by reference to the following drawings, in which:

Fig. 1 is a general view of the method according to the present invention,

Fig. 2 shows more detail of the general view of the method according to the present invention,

Fig. 3 shows the preparation of medical two-dimensional image data,

Fig. 4 shows the generation of a three-dimensional patient model,

Fig. 5 shows an inversion model,

Fig. 6 shows a three-dimensional reference model, and

Fig. 7 shows a three-dimensional implant model.

As an example, the case of a patient will be illustrated who has a complicated large area defect (for example, resulting from an accident, a tumor etc.) in the upper half of the cranium. In Fig. 1 and 2 there are represented both, a general block diagrammatical overview and a detailed block diagrammatical overview to illustrate the method according to the present invention.

For a precise diagnosis and for a later implant generation medical two-dimensional image data 1 (two-dimensional tomograms) of a defect area 5 and of the environment of the same (refer to Fig. 3) are taken from a patient in a radiological hospital department (for example by computer tomography or by nuclear magnetic resonance tomography). By use of a mathematical image processing algorithm at first a contour detection is made in the two-dimensional image data 1 and subsequently a segmentation is carried out with the aim to detect the hard tissue ranges (bones). As a result of the contour detection and segmentation two-dimensional image data 2 are obtained via which, by a respective spatial arrangement, a virtual three-dimensional patient model 3 (dotted model) is formed at least of the defect area 5 and environment.

In a cooperation between a physician and a design engineer the defect area is precisely defined and marked in this virtual three-dimensional patient model 3 by utilizing user-specific computer programs especially applicable for this purpose.

In the next step, the implant design engineer has several methods at his disposal for generating precisely fitting implants. These methods are:

1. When in a three-dimensional patient model 4 (shown in a cross-sectional view in Fig. 5), the defect area 5 is completely located in one body half, that is, entirely in one head side, then the data of this body side with the defect area 5 can, by inversion, be reconstructed, making use of the bilateral symmetry of the human body, from the data of the undamaged side 7 of the three-dimensional patient model 4 (imaging of the undamaged side 7 at the plane of symmetry 6). After inversion, an extraction of a virtual implant model 9 is carried out by use of mathematical algorithms which will here not be referred to in more detail.

2. When in a three-dimensional patient model 10 (shown in a lateral view in Fig. 6), the defect area 5 is located in the plane of symmetry of the human body or the data of the undamaged side cannot be utilized, somehow or other, then the virtual implant model 9 can be generated via a three-dimensional reference model 11. To this end, specific features of the three-dimensional patient model 10 are compared to a reference database and a selection of similar models is made under consideration of mathematical, functional, medical and aesthetic aspects. Then, the three-dimensional reference model 11 is selected from this range of models, preferably under particular consideration of the medical expert opinion. By superimposing the three-dimensional reference model 11 and the three-dimensional patient model 10 to one another, a virtual three-dimensional patient model 12 will be obtained, from which, in turn, the virtual implant model 9 will be generated by computer, as described under item 1.

3. In special cases, when for example the defect partially lies in the plane of symmetry, both methods (inversion according to item 1 and database comparison according to item 2) can be used one after the other and the results will be combined to a three-dimensional reference model for the implant modeling.

The selection and/or the shaping of the three-dimensional reference model after at least one of the methods mentioned hereinabove and the generation of the virtual implant model from the three-dimensional reference model are performed merely by computation. By this processing both, a very rapid and a very precisely fitting generation and subsequent manufacture of the implant for the operative insert on the patient is given.

The present virtual implant model 9 (Fig. 7) is subjected to various procedures after its generation. Said procedures may include, for example, strength calculations, simulations for the medical operation planning and the manufacture, as well as providing markings (bore holes, fixings or the like), quality control etc.

After designing the virtual implant model 9, a generation/simulation of the CNC-data for the physical implant manufacture and the transfer of the virtual implant model into a usable implant are carried out.

LIST OF REFERENCE NUMERALS

1	-	medical two-dimensional image data
2	-	contour detection and segmentation two-dimensional image data
3	-	three-dimensional patient model (dotted model)
4	-	three-dimensional patient model (cross-section)
5	-	defect area
6	-	plane of symmetry of human body
7	-	undamaged side of the three-dimensional patient model
8	-	inversion of undamaged side 7
9	-	(virtual) implant model
10	-	three-dimensional patient model (lateral view)
11	-	three-dimensional reference model
12	-	(virtual) three-dimensional patient model

CLAIMS

1. Method for generating a patent-specific implant, in which a virtual three-dimensional model is generated from the image data taken at least from the implant area and its environment obtained from the patient and the implant is manufactured by virtue of CNC-data for the operative use on the patient, characterized in that the virtual three-dimensional model of the patient is compared to real medical reference data, and therefrom the best suited for the patient and a reference model object, respectively, best resembling the model of the patient are selected or formed, and in that a virtual implant model is generated by said reference model object, and in that the virtual data of the implant model are used as control data for a program controlled manufacture of the implant.

2. Method as claimed in claim 1, characterized in that the virtual three-dimensional model of the patient is compared to real medical reference data of a database and from these data stored in the database a reference model best suited for the patient and best resembling the model of the patient, respectively, is selected.

3. Method as claimed in claim 2, characterized in that at first a plurality of reference models objects resembling the model of the patient are selected from the data stored in the database and from the selected ones a reference model object best suited for the patient and mostly resembling the model of the patient, respectively, is

selected under consideration of further selection criteria such as medical expert opinion.

4. Method as claimed in claim 1, characterized in that the virtual three-dimensional model of the patient is compared with data from the patient him/herself preferably under consideration of body symmetry, in particular of mirror-symmetrical body ranges being doubly present and/or under consideration of older data from the patient and that from these data a reference model object best suited for the patient and most resembling the model of the patient, respectively, is selected or formed.

5. Method as claimed in claims 1, 2, and 4, characterized in that the virtual three-dimensional model of the patient is compared both, with the real medical reference data of a database and with the data from the patient him/herself, and in that from all these data a reference model object best suited for the patient and most resembling the model of the patient, respectively, is selected or formed.

ABSTRACT

The invention relates to a method for generating patient-specific implants from the results of an examination of a patient arising from an imaging method in medical technology. The aim of the invention is to generate an implant which is functionally and aesthetically adapted to the patient with a greater degree of precision, irrespective of the size, form and complexity of the defect, whereby said implant can be produced and operatively inserted into the patient over a short time period and in a simple manner. According to the invention, a virtual three-dimensional model of the patient which is formed from existing recorded (two-dimensional) image data of a patient known per se is compared with real medical reference data. Said comparison which is, for example, carried out using a data bank with test person data enables a reference model object which is most suited to the patient or closest to the patient model to be selected or formed and a virtual implant model is generated accordingly. CNC control data is directly generated from the implant model which is generated virtually in the computer for program-assisted production of said implant.

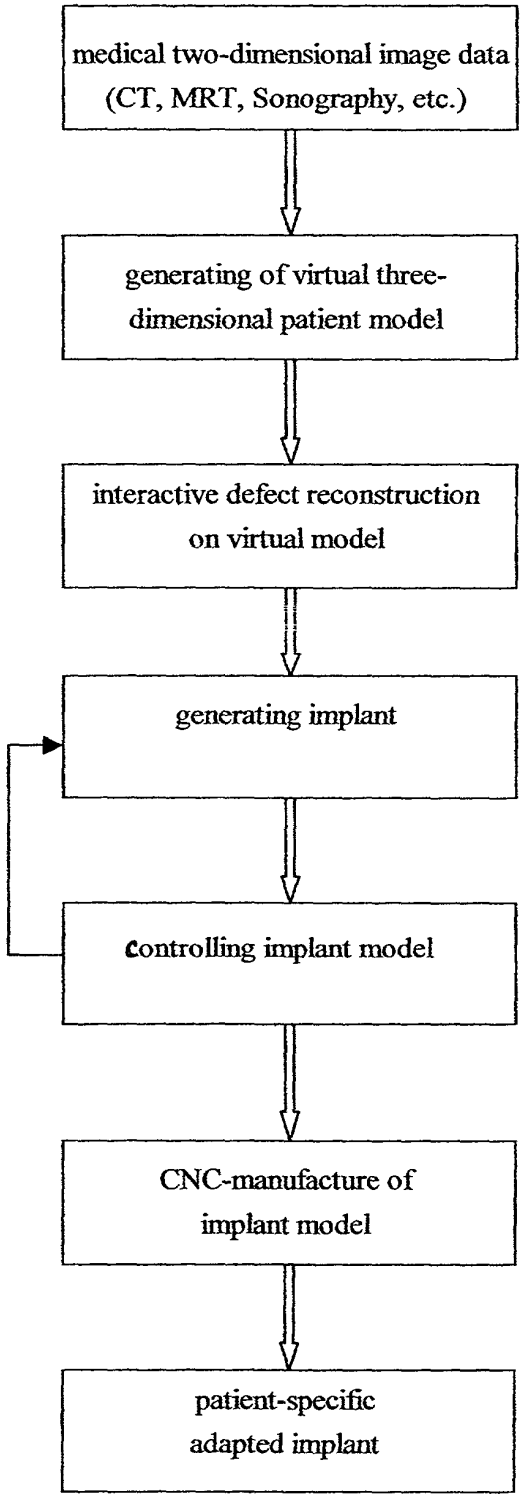
medical two-dimensional image data (CT, MRT, Sonography, etc.)
generating of virtual three-dimensional patient model
interactive defect reconstruction on virtual model
generating implant
controlling implant model
CNC-manufacture of implant model
patient-specific adapted implant

Fig. 1

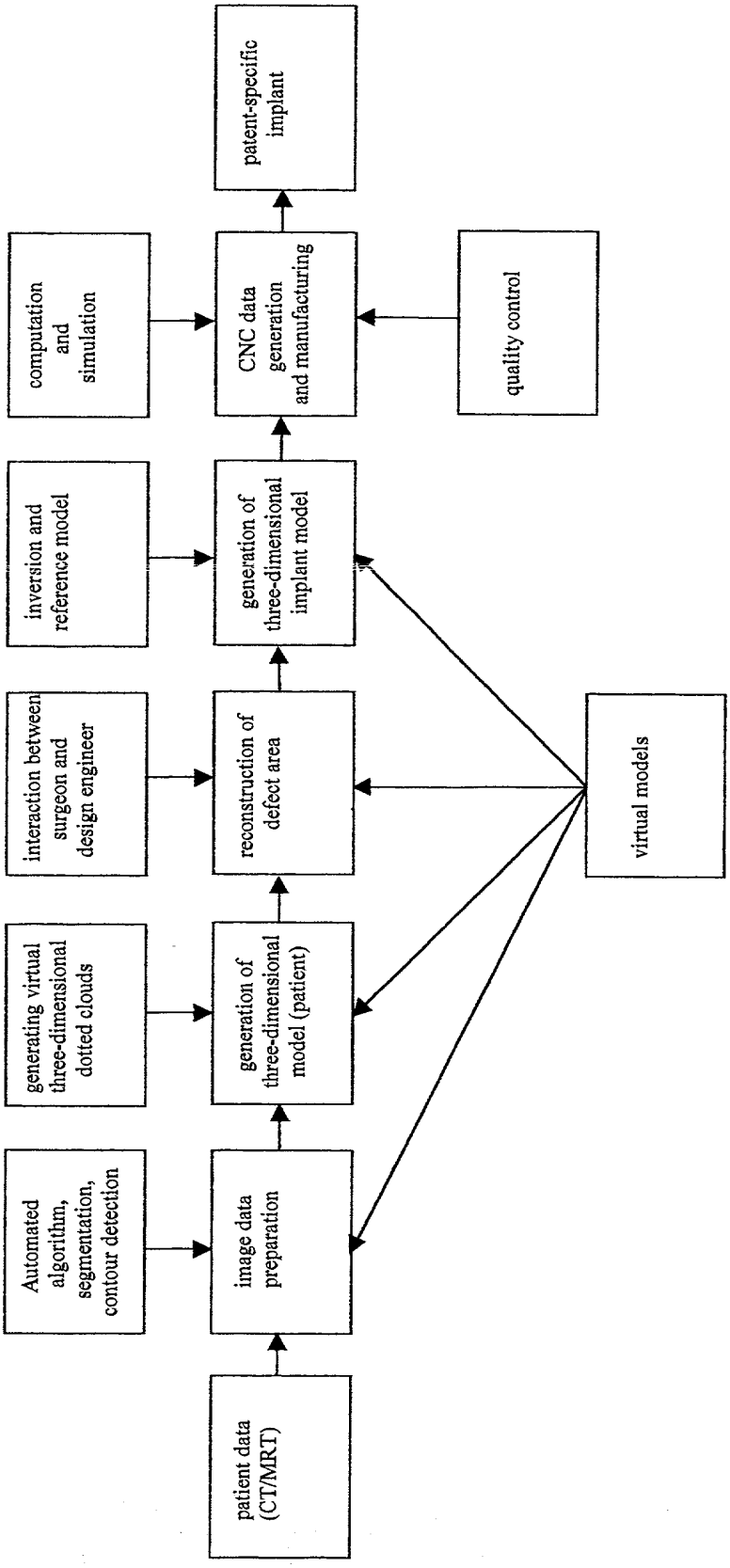
patent-specific implant
computation and simulation
CNC data generation and manufacturing
quality control
inversion and reference model
generation of three-dimensional implant model
interaction between surgeon and design engineer
reconstruction of defect area
virtual models
generating virtual three-dimensional dotted clouds
generation of three-dimensional model (patient)
Automated algorithm, segmentation, contour detection
image data preparation
patient data (CT/MRT)

Fig. 2

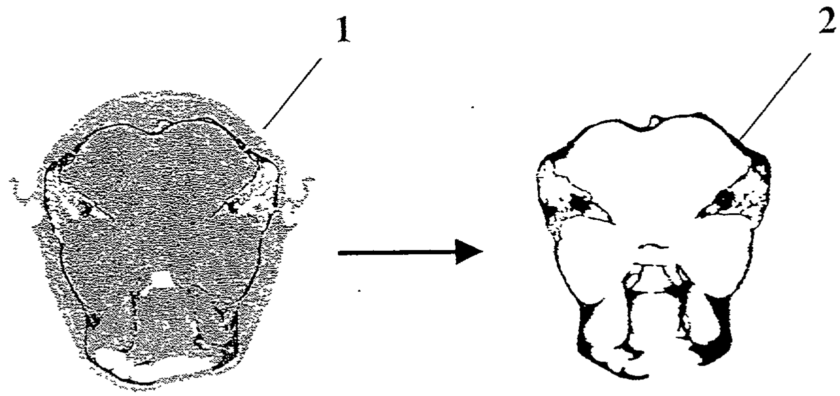

Fig. 3

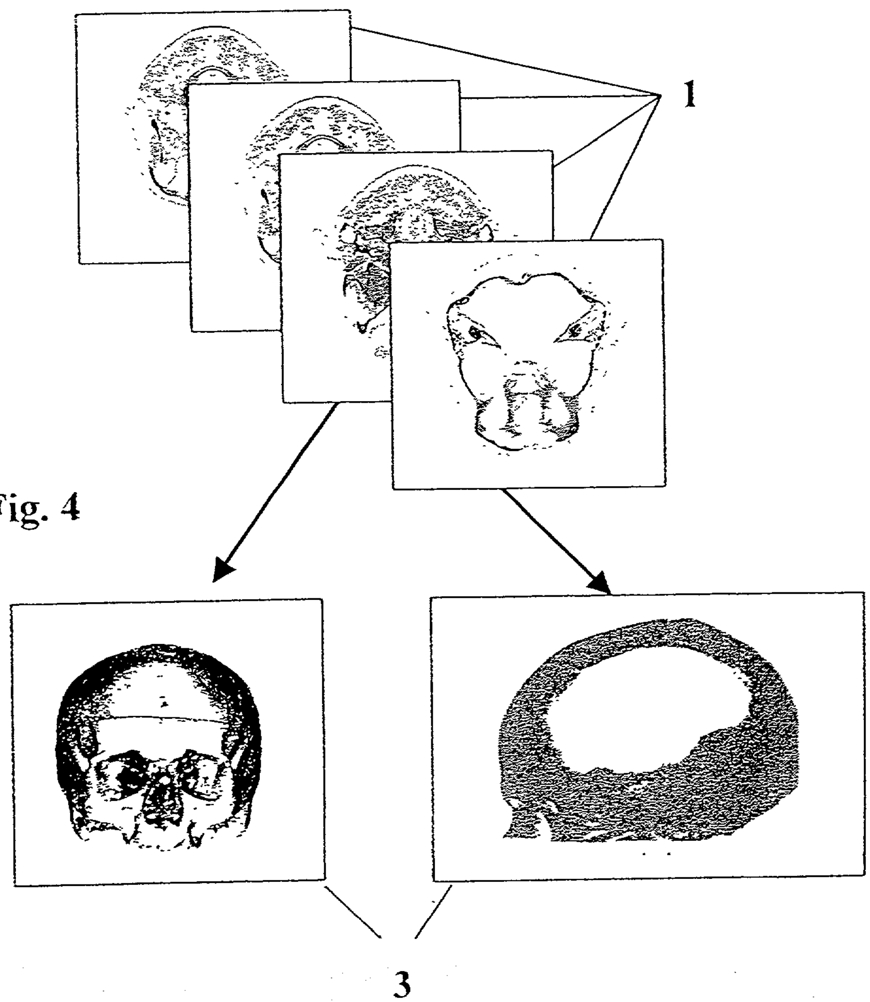

Fig. 4

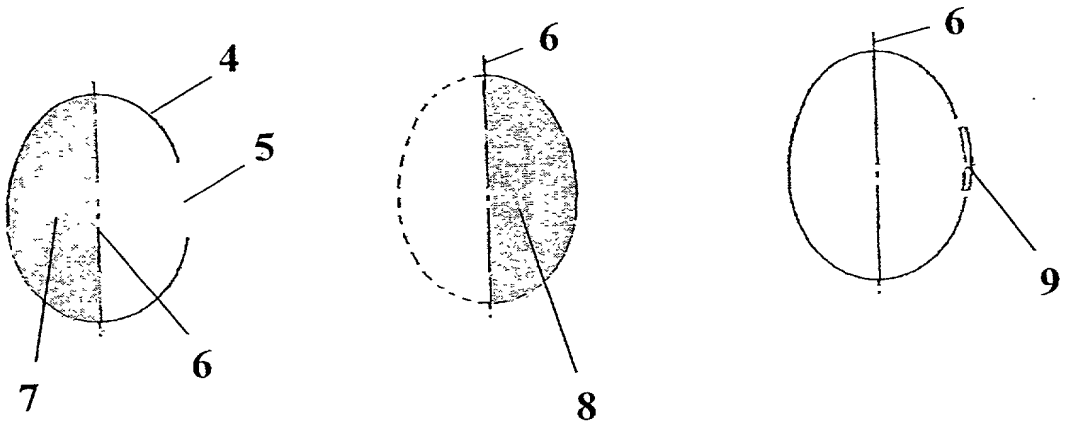

Fig. 5

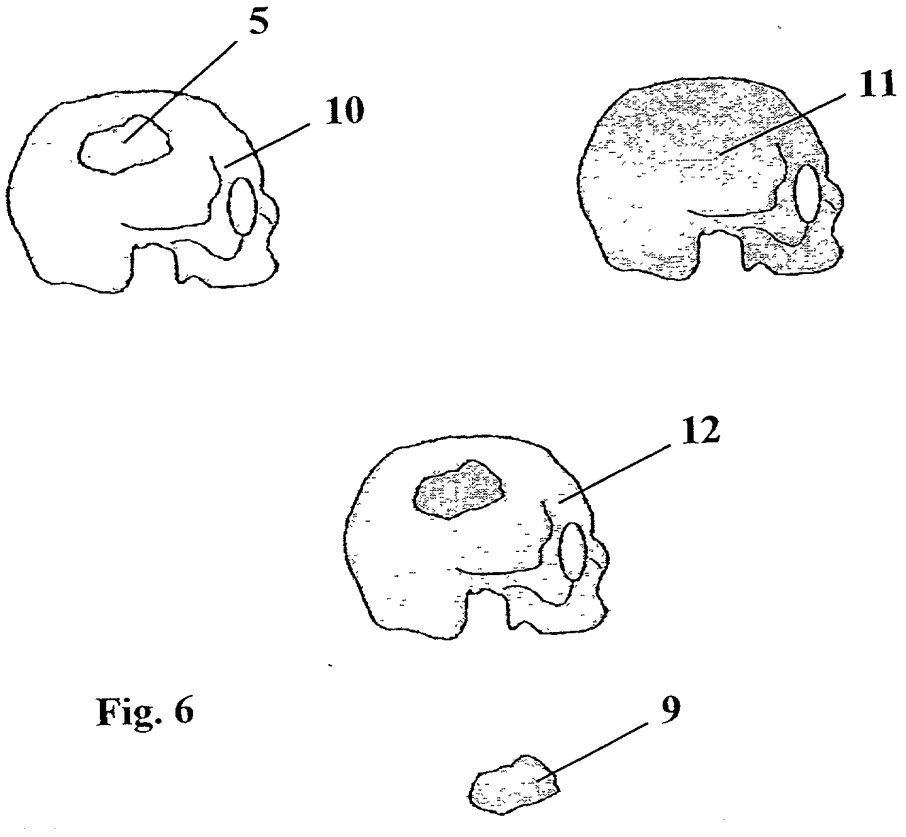

Fig. 6

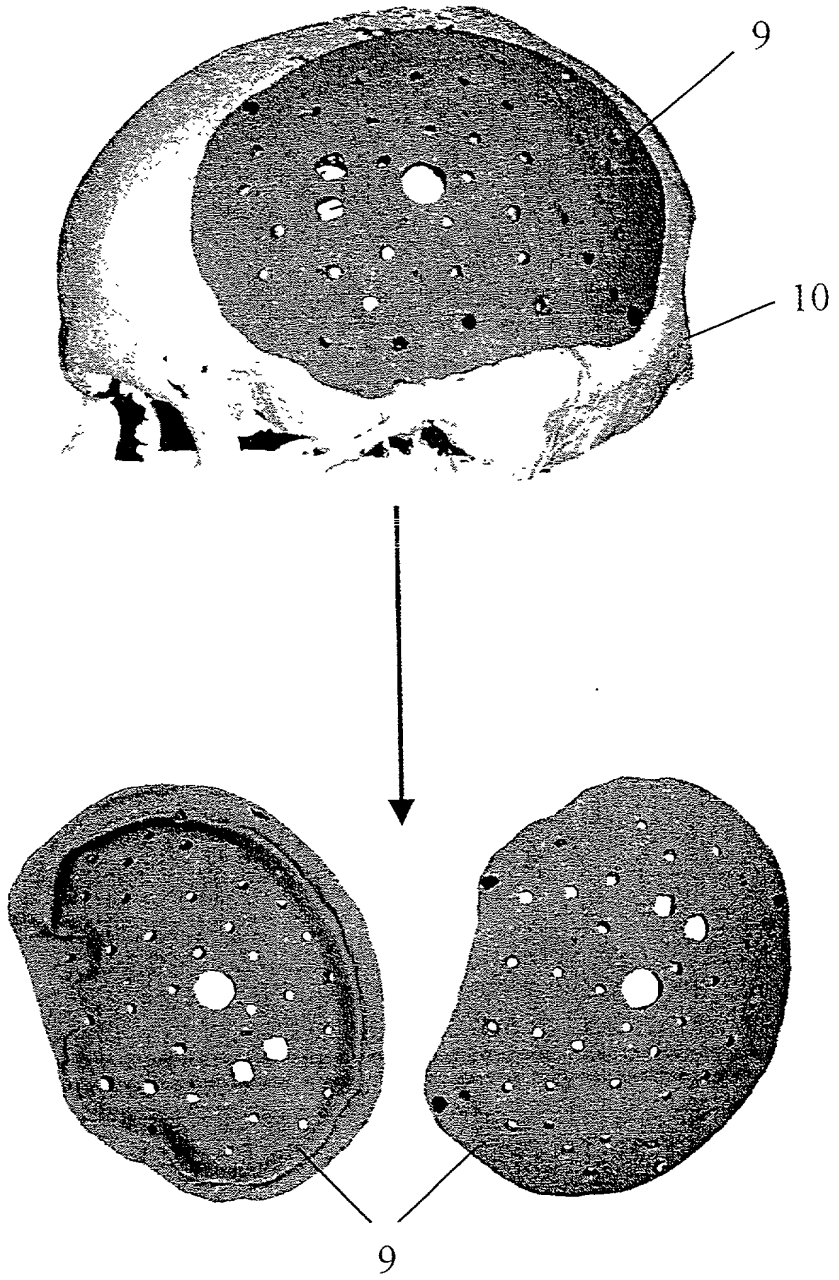

Fig. 7

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)	Attorney's Docket Number

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"METHOD FOR GENERATING PATIENT-SPECIFIC IMPLANTS"

the specification of which (check only one item below):

[ ] is attached hereto.

[ ] was filed as United States application
Serial No. _____
on _____,
and was amended
on _____ (if applicable).

[X] was filed as PCT international application
Number **PCT/EP00/04166**
on May 10, 2000
and was amended under PCT Article 19
on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C 119:			
Country (if PCT indicate "PCT")	Application Number	Date of Filing (day, month, year)	Priority Claimed Under 35 USC 119
DE	199 22 279.7	11.05.1999	[X] Yes [ ] No
			[ ] Yes [ ] No
			[ ] Yes [ ] No
			[ ] Yes [ ] No
			[ ] Yes [ ] No

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Continued) (Includes Reference to PCT International Applications)	Attorney's Docket Number

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check One)		
U.S. Application Number	U. S. Filing Date	Patented	Pending	Abandoned

PCT APPLICATIONS DESIGNATING THE U.S.					
PCT Application No.	PCT Filing Date	U.S. Serial Numbers Assigned (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Frank J. Jordan	Reg. No. 20,456	Herbert F. Ruschmann	Reg. No. 35,341
C. Bruce Hamburg	Reg. No. 22,389	Marvin Turken	Reg. No. 18,330
Lainie E. Dolinger	Reg. No. 36,123	Alfred D'Andrea	Reg. No. 27,752

Send Correspondence To:	Jordan and Hamburg 122 East 42nd Street New York, New York 10168	Direct Telephone Calls to: C. Bruce Hamburg (212) 986-2340

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full Name of Sole or First Inventor	Inventor's Signature	Date
Peter LITSCHKO	Peter Litschko	12-Nov-2001
Residence		**Citizenship**
Naumburg DEX		German
Post Office Address		
Weingarten 10, D-06618		Germany

Full Name of Second Joint Inventor, if any	Inventor's Signature	Date
Torsten HENNING	Torsten Henning	30-Nov-2001
Residence		**Citizenship**
Jena DEX		German
Post Office Address		
Berghoffsweg 6A, D-07743		Germany

(S) over

3 - 00

Full Name of Sole or First Inventor	Inventor's Signature	Date
Jörg BEINEMANN	x Jörg Beinemann	x 07-Jan-2002
Residence: Weimar DEX		Citizenship: German
Post Office Address: Hoher Weg 11, D-99425 Weimar		Germany

4 - 00

Full Name of Second Joint Inventor, if any	Inventor's Signature	Date
Wolfgang FRIED	x Wolfgang Fried	x 07-Jan.2002
Residence: Jena		Citizenship: German
Post Office Address: Julius-Schaxel-Str. 25, D-07749 Jena		Germany

5 - 00

Full Name of Second Joint Inventor, if any	Inventor's Signature	Date
Werner LINSS	x Werner Linss	07-Jan-2002
Residence: Jena DEX		Citizenship: German
Post Office Address: Sachseneckweg 4, D-07743 Jena		Germany

Full Name of Sole or First Inventor	Inventor's Signature	Date
Residence		Citizenship
Post Office Address		

Full Name of Second Joint Inventor, if any	Inventor's Signature	Date
Residence		Citizenship
Post Office Address		

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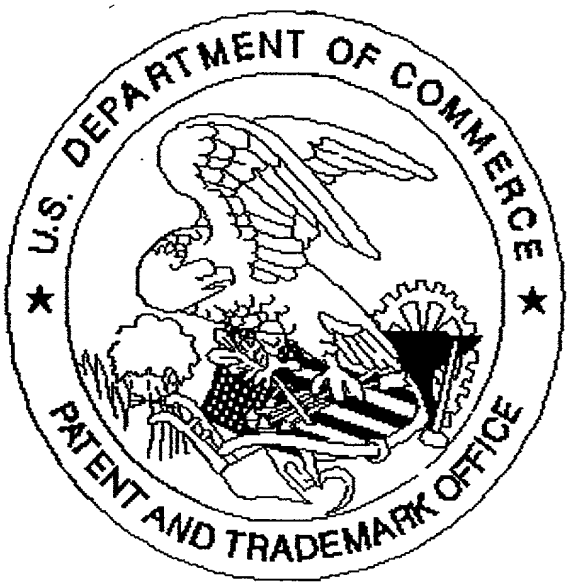

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